

# NATURAL2U

Bringing to market value-added, natural, organic and environmentally conscious brands of unsurpassed integrity.

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September 27, 2002

RECEIVED  
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BY:

Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Notification of § 403(r)(6) Statements**

Gentlemen:

In accordance with 21 C.F.R. § 101.93, Natural2U, LLC of 3133 Orchard Vista Drive, S.E., Grand Rapids, Michigan 49546, hereby provides notification to the Office of Nutritional Products, Labeling and Dietary Supplements that Natural2U, LLC, as distributor of the respective products listed below, has included the following statements on the labels or in the labeling of the respective products, all of which were first marketed less than thirty (30) days ago.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Aloe Vera	Aloe Vera	You may know Aloe Vera for its benefits to promote the healing of damaged skin.
Cayur Smoke Shield	Detox Smoke and Pollution	1. These days, if you drive, smoke or cook, you are subjected to airborne toxins that can wreak havoc with your body. 2. Turmeric, green tea, rosemary, clove and other herbs have been shown to act as herbal free radical scavengers, increasing enzymes that promote detoxification as we live and breathe.

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3133 Orchard Vista Drive, SE . Grand Rapids, MI, 49546 . www.natural2u.com

Also see docket 97S-0163

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Calcium Magnesium Powered Drink Mix Tropical Fruit	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> <li>1. Calcium and Magnesium levels in the body affect the health of your bones and teeth, but they also influence nerve and muscle health and help maintain cardiovascular function and a healthy circulatory system.</li> <li>2. Too little Calcium and Magnesium can also result in restless sleep, increased PMS symptoms, elevated blood pressure, and muscle tension. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.</li> </ol>
Cayur Calcium Magnesium Powered Drink Mix Unflavored	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> <li>1. Calcium and Magnesium levels in the body affect the health of your bones and teeth, but they also influence nerve and muscle health and help maintain cardiovascular function and a healthy circulatory system.</li> <li>2. Too little Calcium and Magnesium can also result in restless sleep, increased PMS symptoms, elevated blood pressure, and muscle tension. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.</li> </ol>
Cayur Calcium Magnesium Powered Drink Mix Hot Apple Cider	Calcium Magnesium Powered Drink Mix	<ol style="list-style-type: none"> <li>1. Calcium and Magnesium levels in the body affect the health of your bones and teeth, but they also influence nerve and muscle health and help maintain cardiovascular function and a healthy circulatory system.</li> <li>2. Too little Calcium and Magnesium can also result in restless sleep, increased PMS symptoms, elevated blood pressure, and muscle tension. Calcium Magnesium Powered Drink Mix is completely soluble, ensuring fast absorption and utilization of the body.</li> </ol>
Cayur Headache Relief	Headache Relief	<ol style="list-style-type: none"> <li>1. Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to relieve headache discomfort..</li> </ol>
Cayur Herbal InflaRelief	Herbal InflaRelief	<ol style="list-style-type: none"> <li>1. Herbal InflaRelief promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation.</li> <li>2. And, besides promoting normal cell growth, these herbs</li> </ol>

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
		help to neutralize free radicals.
Cayur Probiotic Complex	Probiotic Complex	<ol style="list-style-type: none"> <li>1. A first line of protection against potentially harmful microorganisms in your food and environment, probiotics are the healthy bacteria that colonize in your digestive tract.</li> <li>2. Probiotic Complex consists of the eight best researched, stable strains of friendly flora, including Lactobacillus acidophilus.</li> <li>3. And we've taken the added step of including the bacterial by-products, now known to be intrinsically beneficial to digestive health.</li> </ol>
Cayur Restful Sleep	Restful Sleep	<ol style="list-style-type: none"> <li>1. Your periods of deep sleep will be longer and more replenishing.</li> <li>2. You will awake more rested and refreshed. Restful Sleep... an herbal lullaby</li> </ol>
Cayur Ultimate Ginger	Ginger	The world's most potent, certified organic ginger extract, with 250 times the concentration for fresh ginger.
Cayur Ultimate Saw Palmetto Complex	Saw Palmetto	<ol style="list-style-type: none"> <li>1. Ultimate Saw Palmetto Complex which includes saw palmetto, green tea, pumpkin seed oil, ginger, and other herbs, may prove to be the best way to support prostate health.</li> <li>2. And by inhibiting the enzyme that promotes prostate swelling, urinary and sexual health are enhanced.</li> </ol>

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Woman's Balance	Cayur Woman's Balance	1. Woman's Balance supports normal hormone levels and bone health for pre-menopausal and post-menopausal women.  2. Black cohosh is Europe's most popular phytoestrogenic tonifying herb.  3. And, vitex has been shown to promote hormone balance, while schizandra promotes normal body secretions.  4. Phytonutrient-rich evening primrose oil is added for its value in maintaining hormonal health.
Cayur B-Complex	Vitamin B	Vitamin B helps your body use energy from fats, carbs and proteins.
Cayur Beauty Complex	Beauty Complex	Collagen, biotin, glycine, and L-cysteine are involved in supporting the health of your skin, hair and nails.
*Cayur Bone Support	Bone Support	Bone Support with 300mg of ipriflavone and a dose of Vitamin D will help your body absorb and metabolize calcium.
Cayur C-500	C-500	Vitamin C can help protect the body from the damaging effects of free radicals.
Cayur Chewable Vitamin C with Acerola	Chewable C Acerola	1. You need Vitamin C for tissue growth and repair, iron, absorption and immunity.  2. Vitamin C can help protect the body from the damaging effects of free radicals.
Cayur Chewable Calcium + D	Chewable Calcium + D	Calcium sourced from oyster shells with added Vitamin D will help maintain bone density and promote nerve and muscle health.
Cayur Chewable Fiber	Chewable Fiber	A balanced blend of soluble and insoluble fibers from multiple sources helps to ensure proper digestive health.

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BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Chewable Iron	Chewable Iron	<ol style="list-style-type: none"> <li>1. Iron is required for the formation of hemoglobin which carries oxygen in the blood.</li> <li>2. Easy-to-digest, flavored tablets help increase stamina.</li> </ol>
Cayur Chewable Lecithin + E	Chewable Lecithin + E	<ol style="list-style-type: none"> <li>1. Lecithin is required for the normal function of cell membranes.</li> <li>2. Vitamin E is a powerful antioxidant that helps to protect cell membranes from free radical damages.</li> </ol>
Cayur Chewable Protein	Chewable Protein	Protein builds and repairs muscles, plays a role in forming hormones, antibodies and tissues - these are the functions of protein.
Cayur Chewable Children's Cal Mag	Chewable Children's Cal Mag	Together, calcium and magnesium affect the health and strength of teeth and bones, and influence nerve and muscle health.
Cayur Chewable Children's Natural C	Chewable Children's Natural C	Our flavorful Chewable C is easy-to-digest, and helps support body tissues and a healthy immune system.
Cayur Chromium Picolinate	Chromium Picolinate	Chromium Picolinate is intended to help your body use food and carbs more evenly throughout the day to help with the highs and lows.
Cayur Complete Calcium	Complete Calcium	<ol style="list-style-type: none"> <li>1. Your bones need calcium. Magnesium helps your body take it in.</li> <li>2. So we paired the two, plus added other minerals to bring the benefits of two, 8-ounce glasses of milk a day in just three tablets.</li> </ol>
Cayur Garlic	Garlic	<ol style="list-style-type: none"> <li>1. Garlic has been used for centuries to support cardiovascular health.</li> <li>2. We've added a special enteric coating to allow each tablet to pass through the stomach into the intestines to promote absorption of garlic's key component, allicin.</li> </ol>
Cayur CoQ10	CoQ10	CoQ10 plays a crucial role in the generation of cellular energy supporting the immune system and healthy circulation.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Echinacea Blend	Echinacea Blend	Our Echinacea Blend contains both Echinacea, angustifolia and purpurea to provide a wide array of benefits for your immune system.
Cayur Ginkgo Biloba	Ginkgo Biloba	<ol style="list-style-type: none"> <li>1. Ginkgo Biloba promotes blood circulation to the brain and extremities, and is helpful for ordinary age-related memory loss.</li> <li>2. It may also be useful for mild dizziness and general cognitive function.</li> </ol>
Cayur Glucosamine Complex	Glucosamine Complex	<ol style="list-style-type: none"> <li>1. Involved in the formation of nails, tendons, skin and ligaments, glucosamine is essential.</li> <li>2. Glucosamine is believed helpful in supporting normal joint function and healthy connective tissue.</li> </ol>
Cayur Iron+Folic Acid	Iron+Folic Acid	Additionally these nutrients are important in maintaining healthy blood cells.
Cayur Menopause Formula	Menopause Formula	Black Cohosh and soy isoflavones have been widely studied for supporting overall well-being and softening the effects of menopause.
Cayur Milk Thistle	Milk Thistle	Silymarin promotes healthy liver function and aids in detoxification of the body.
Cayur C Plus	C Plus	<ol style="list-style-type: none"> <li>1. You need Vitamin C for tissue growth and repair, iron absorption and immunity.</li> <li>2. Vitamin C can help protect the body from the damaging effects of free radicals.</li> </ol>
Cayur Complete Antioxidant	Complete Antioxidant	Six antioxidants including pycnogenol, grape seed extract, green tea extract and turmeric form a nice little task force to help protect your body by neutralizing free radicals.
Cayur Zinc	Zinc	Zinc contributes to a healthy immune system and the healing of wounds by aiding the body in the synthesis of protein and formation of collagen.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
Cayur Bilberry	Bilberry	1. Bilberry strengthens blood vessels, especially important in the area of the retina called the macula.  2. Bilberry also helps maintain normal nighttime vision.
Cayur Omega 3	Omega 3	EPA helps support healthy blood triglyceride (fat) levels, healthy blood flow and joint mobility. DHA helps support optimal memory, learning and concentration.
Cayur Passionflower	Passionflower	Passionflower has been used for centuries as a soothing and calming herb for restlessness.
Cayur PMS Formula	PMS Formula	Adding GLA to your diet may provide gentle relief from cramps, breast tenderness, irritability and water retention.
Cayur Saw Palmetto	Saw Palmetto	Saw palmetto supports normal urinary flow and prostate health.
Cayur Siberian Ginseng	Siberian Ginseng	1. Currently being studied for its ability to increase work endurance and improve blood flow to the brain, Ginseng is believed to provide mental energy.
Cayur St.John's Wort	St.John's Wort	One of the longest used herbs, mood enhancing St. John's Wort gradually builds in your body to help restore a sense of balance in your life.
Cayur Vitamin E with Selenium	Vitamin E with Selenium	Vitamin E and Selenium work together to support cardiovascular health.
Cayur Valerian	Valerian	1. Valerian provides a safe, natural solution for occasional sleeplessness.  2. Valerian root has been clinically proven to help you fall asleep faster, and stay asleep.
Cayur Digestive Aid	Digestive Aid	1. Digestive Aid contains enzymes that help you digest dairy, carbohydrate, starches and fats.  2. Better digestion, less distress from gas and bloating - better day.

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The undersigned, on behalf of Natural2U, LLC, hereby certifies that the information contained in this notice is complete and accurate and that Natural2U, LLC has appropriate substantiation that the statements are truthful and not misleading.

Should any questions arise about the information conveyed hereby, please do not hesitate to contact us. We appreciate your attention to these matters.

NATURAL2U, LLC

By: Jennifer Wolke

Its: Director of Product Development

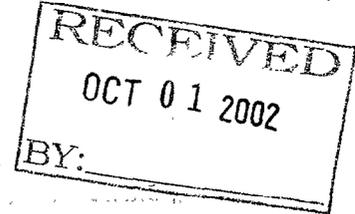
cc: Mr. Steve Kluting  
Varnum, Riddering, Schmidt & HowlettLLP

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BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage PMS Peacemaker	Evening Primrose & Borage Blend	Adding a blend of GLA (gamma-linolenic acids) from oils of Evening Primrose and Borage to your diet may provide gentle relief from cramps, breast tenderness, irritability and water retention.
iVillage Headache Rescue	Feverfew Complex	Throughout history, feverfew, rosemary, lavender, willow and other herbs have been used to relieve headache discomfort.
iVillage Stand Tall	Calcium Multimineral	1. Your bones need calcium. Magnesium helps your body take it in. 2. So we paired the two, plus added other minerals to bring the benefits of two, 8-ounce glasses of milk a day in just three tablets.

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BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Hormone Harmony	Black Cohosh Blend	<ol style="list-style-type: none"> <li>1. Hormone Harmony supports normal hormone levels and bone health for pre-menopausal and post-menopausal women.</li> <li>2. And vitex has been shown to promote hormone balance, while schizandra promotes normal body secretions.</li> <li>3. Phytonutrient-rich evening primrose is added for its value in maintaining hormonal health.</li> </ol>
iVillage Cell Saver	CoQ10	<ol style="list-style-type: none"> <li>1. Co-Q10 plays a crucial role in the generation of cellular energy, supporting the immune system and healthy circulation.</li> <li>2. A complement of L-carnitine and taurine improves Co-Q10's effectiveness.</li> </ol>
iVillage Waist Management	Chromium Picolinate	Chromium Picolinate is intended to help your body use food and carbs more evenly throughout the day to help with the highs and lows.
iVillage Seriously C	Vitamin C-500	<ol style="list-style-type: none"> <li>1. You need Vitamin C for connective tissue formation and maintenance and to strengthen your resistance.</li> <li>2. Vitamin C can help increase iron absorption and protect the body from the damaging effects of free radicals.</li> </ol>
iVillage Memory Blast	Ginkgo Biloba	<ol style="list-style-type: none"> <li>1. Ginkgo Biloba promotes blood circulation to the brain and extremities, and is helpful for ordinary age-related memory loss.</li> <li>2. It may also be useful for mild dizziness and general cognitive function.</li> </ol>
iVillage Mighty C for Kids	Chewable Vitamin C	Our flavorful Chewable C is easy-to-digest, and help support body tissues and a healthy immune system.
iVillage Beauty Queen	Biotin and Collagen Complex	Collagen, biotin, glycine, and L-cysteine are involved in supporting the health of your skin, hair and nails.
iVillage Merry Mood	St John's Wort	One of the longest used herbs, mood enhancing St. John's Wort gradually builds in your body to help restore a sense of balance in your life.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Cool Down	Black Cohosh Menopause Formula	Black Cohosh and soy isoflavones have been widely studied for supporting overall well-being and softening the effects of menopause.
iVillage Immunity Patrol	Echinacea Blend	Our Echinacea Blend containing both Echinacea angustifolia and Echinacea purpurea provides a wide array of benefits for your immune system.
iVillage B Healthy	B-Complex	Vitamin B helps your body use energy from fats, carbs and proteins.
iVillage Garlic Goodness	Garlic Concentrate	<ol style="list-style-type: none"> <li>1. Garlic has been used for centuries to support cardiovascular health.</li> <li>2. We've added a special enteric coating to allow each tablet to pass through the stomach into the intestines to promote absorption of garlic's key component, allicin.</li> </ol>
iVillage Glide in Your Stride	Glucosamine Blend	<ol style="list-style-type: none"> <li>1. Involved in the formation of nails, tendons, skin and ligaments, glucosamine is vital.</li> <li>2. Glucosamine is believed helpful in supporting normal joint function and healthy connective tissue.</li> </ol>
iVillage Invisible Shield	Antioxidant	Six antioxidants including pycnogenol, grape seed extract, green tea extract and turmeric form a nice little task force to help protect your body by neutralizing free radicals.
iVillage Mind-Body Connection	Omega 3	EPA helps support healthy blood triglyceride (fat) levels, healthy blood flow and joint mobility DHA helps support optimal memory, learning and concentration.
iVillage Sunny C	Vitamin C Plus	<ol style="list-style-type: none"> <li>1. You need Vitamin C for connective tissue formation and maintenance and to strengthen your resistance.</li> <li>2. Vitamin C can help increase iron absorption and protect the body from the damaging effects of free radicals.</li> </ol>
iVillage Energy Up	Siberian Ginseng	Ginseng is being studied for its ability to increase work endurance.
iVillage Bone Support	Ipriflavone Blend	300 mg of ipriflavone and a dose of Vitamin D will help your body absorb and metabolize calcium.

BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Mommy Must-Have	Iron+Folic Acid	Additionally these nutrients are important in maintaining healthy blood cells.
iVillage See Clearly	Bilberry	<ol style="list-style-type: none"> <li>1. Bilberry strengthens blood vessels, especially important in the area of the retina called the macula.</li> <li>2. Bilberry also helps maintain normal nighttime vision.</li> </ol>
iVillage Smooth Movin'	Joint Support	<ol style="list-style-type: none"> <li>1. Smooth Movin promotes healthy joint function by inhibiting the COX-2 enzyme, associated with joint inflammation.</li> <li>2. Our formula actually supports stomach and liver health.</li> <li>3. And, besides promoting normal cell growth, these herbs help to neutralize free radicals.</li> </ol>
iVillage Restful Sleep	Herbal Relief	<ol style="list-style-type: none"> <li>1. Your periods of deep sleep will be longer and more replenishing.</li> <li>2. You will awake more rested and refreshed.</li> </ol>
iVillage Tummy Tranquility	Ginger Complex	<ol style="list-style-type: none"> <li>1. If you're among the millions who believe in ginger's ability to support stomach, liver and intestinal health, you'll love Tummy Tranquility.</li> <li>2. And, we've added rosemary extract, historically used for its antioxidant properties.</li> </ol>
iVillage Pollution Patrol	Turmeric Complex	Turmeric, green tea, rosemary, clove and other herbs have been shown to act as herbal free radical scavengers, supporting the neutralizing process.

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BRAND NAME	NAME OF DIETARY SUPPLEMENT	TEXT OF THE STATEMENT(S)
iVillage Bone Brew	Plain Calcium Drink	<ol style="list-style-type: none"> <li>1. Calcium and Magnesium are important in promoting the health of bones and teeth.</li> <li>2. These minerals are essential for the contraction and relaxation of muscles, and can ease the feeling of tension that can lead to a host of discomforts.</li> <li>3. Calcium and Magnesium also play a critical role in maintaining an already healthy blood pressure.</li> <li>4. iVillage Calcium Magnesium Drink Mix dissolves completely, ensuring proper absorption and utilization by the body.</li> </ol>
iVillage Bone Brew	Pineapple Guava Calcium Drink	<ol style="list-style-type: none"> <li>1. Calcium and Magnesium are important in promoting the health of bones and teeth.</li> <li>2. These minerals are essential for contraction and relaxation of muscles, and can ease the feeling of tension that can lead to a host of discomforts.</li> <li>3. Calcium and Magnesium also play a critical role in maintaining an already healthy blood pressure.</li> <li>4. iVillage Calcium Magnesium Drink Mix dissolves completely, ensuring proper absorption and utilization by the body.</li> </ol>
iVillage Take It to Heart	Vitamin E with Selenium	Vitamin E and Selenium work together to support cardiovascular health.

The undersigned, on behalf of Natural2U, LLC, hereby certifies that the information contained in this notice is complete and accurate and that Natural2U, LLC has appropriate substantiation that the statements are truthful and not misleading.

Office of Nutritional Products  
September 27, 2002  
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Should any questions arise about the information conveyed hereby, please do not hesitate to contact us. We appreciate your attention to these matters.

NATURAL2U, LLC

By: Jenny Wolters  
Its: Director of Product Development

cc: Mr. Steve Kluting  
Varnum, Riddering, Schmidt & HowlettLLP

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